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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,285

11/13/2003

Wamis Singhatat

ZL 0195

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23367

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09/07/2007

GENE WARZECHA

LINVATEC CORPORATION

11311 CONCEPT BOULEVARD

LARGO, FL 33773

EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,285

Applicant(s)

SINGHATAT, WAMIS

Examiner

Timothy J. Neal

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-12, 14, 15, 19-22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-12, 14, 15, 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendments filed on 5/07/2007.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6-12, 14, 15, and 19-21, drawn to a suture anchor, classified in class 606, subclass 232.
- II. Claims 22 and 24-26, drawn to a method of securing suture to tissue, classified in class 606, subclass 72.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method as amended does not include all of the particulars of the apparatus. Also, the apparatus can be used in a different method. The limitation regarding the simultaneous reduction of the aperture gripping the suture during insertion of the anchor creates a patentable distinction between the method and apparatus. The apparatus may be used by simply closing the aperture before insertion in the body. Also, the anchor does not need to be used in body tissue but could be used for a variety of fastening jobs.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Gene Warzecha on 8/27/2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-4, 6-15, and 19-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22 and 24-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-12, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. Claim 1 recites "the proximal portion being responsive to insertion into the body tissue to move from the open to the closed position". The Examiner can find no support for this limitation. Claim 13, now cancelled, only stated that the body portion was deformable. The current claim is narrower. Therefore, the claims are considered to contain new matter not contained in the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **1-4, 6-12, and 14** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As stated above, claim 1 recites "the proximal portion being responsive to insertion into the body tissue to move from the open to the closed position". The use of the word "responsive" is not clear. Because the term has not been used in the specification, the Examiner has no context for the word from the disclosure. The term suggests that upon insertion of the anchor into the body the proximal portion reacts by closing. This is not in the disclosure so the Examiner does not consider this to be an accurate interpretation of the claim. The scope of the claim can, therefore, not be determined.

Claim 12 is further considered indefinite because it refers to the suture. The suture has not yet been positively recited. Therefore, further limiting the sutures

structure is indefinite. The Applicant should positively recite the suture before describing it.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12, 14, 15, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (US 6,293,961).

Schwartz discloses a distal body portion (20, distal portion), a proximal body portion (24) with opposed gripping portions (36 and 37) defining a suture receiving aperture (30) transverse to the longitudinal axis, a channel (22), the anchoring member includes an annular ring (distal most portion of 20 is an annular ring), a locking mechanism (36 and 37 portions that lock into each other, also disclosed are multiple teeth and grooves, one set could be the gripping portions and another set the locking mechanism), and in the open position the proximal portion is non-circular and is circular in the closed position (figure 9). The locking mechanism contains a male/female engagement mechanism (figure 9). The suture anchor is bioabsorbable (Column 2 Lines 25-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '961.

The Examiner considers Schwartz to anticipate the claims as stated above. However, because the particular shape of the device is not necessarily clear, the Examiner is providing an alternative rejection. The claims are drawn to the shape of the device, which is generally not considered to differentiate an application over the prior art. The Examiner considers the Schwartz to contain three options for the cross-sectional shape of the proximal body portion when in the open and closed positions. Either the proximal portion is oval in the open position and circular in the closed position or the proximal portion is circular in the open position and oval in the closed position or the proximal portion is oval in both positions. One having ordinary skill in the art would be able to modify the device to either of these configurations without changing the effect of the device. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Schwartz's device to include the shape as claimed. Such a modification is not considered to be non-obvious to a person of ordinary skill.

Response to Arguments

Applicant's arguments with respect to claims 1, 15, and their dependent claims have been considered but are moot in view of the new ground(s) of rejection.

The Applicant has argued Yarnitsky does not anticipate the claims. The Examiner has removed Yarnitsky. The Examiner notes the language of claim 1 regarding the 112 rejections as functional. The Examiner considers Schwartz's device to be capable of closing upon insertion into the body. Also, claims 3 and 4 are considered anticipated by Schwartz. The distal portion can be considered any portion of Item 20. The broad language of the independent claim and the corresponding language of claims 3 and 4 allows the Examiner to consider the distal portion to be defined as described by the claim. Any portion of Item 20 that extends beyond the diameter of portion 24 is not considered to be the distal portion of the suture anchor. The anchoring member is part of the distal portion and the Examiner is following the same logic applied to the interpretation of the distal portion to define the anchoring member. The shape of the proximal portion in the open and closed position is not patentable over the prior art. There is no advantage to one configuration over the other. The rejection sufficiently addresses all other issues.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on (571) 272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN



LOAN H. THANH
PRIMARY EXAMINER